

ACCOMPANYING LABELING: Folder entitled "Directions for the use of Vital B-C Capsules.", reading in part: "Three capsules four times a day before meals and at bedtime."

RESULTS OF INVESTIGATION: The capsules in the above-described shipment were, after arrival at Philadelphia, Pa., repackaged into bottles and labeled as described above.

LIBELED: 6-4-58, E. Dist. Pa.

CHARGE: 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for acne; and 502(j)—the article, because of its content of vitamin A, was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Three capsules four times a day before meals and at bedtime," which were the recommended directions contained in the folder entitled "Directions for the use of Vital B-C Capsules."

DISPOSITION: 8-29-58. Consent—claimed by Daniel Cooperman Pharmacy, Philadelphia, Pa., and relabeled.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5702. Clarimycin (3 seizure actions). (F.D.C. Nos. 41607, 41608, 41609, 41610, 41677. S. Nos. 8-341 P, 11-763 P, 11-866/7 P, 16-789 P.)

QUANTITY: 1,912 display cards, each containing 1 btl., at Highland Park and Detroit, Mich.; 33 display cartons, each containing 6 btls., at Cleveland, Ohio; and 297 btls., at Pittsburgh, Pa.

SHIPPED: Between 12-12-57 and 2-24-58, from Jersey City, N.J., by Meritt Corp.

LABEL IN PART: (Btl.) "Contents 5 drams Clarimycin Anti-biotic Acne Lotion
* * * Active Ingredients: Neomycin Sulphate, Allantoin."

LIBELED: Between 3-3-58 and 4-23-58, E. Dist. Mich., W. Dist. Pa., and N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling of the article in the Cleveland and Pittsburgh lots contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, blackheads, and stubborn skin infections; and 505(a)—the article, in all lots, was a new drug which may not be introduced into interstate commerce, and an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: Between 8-21-58 and 10-21-58. Consent—destruction.

5703. Meprobamate tablets. (F.D.C. No. 41895. S. No. 4-401 P.)

QUANTITY: 1 drum containing 25,000 tablets at Richmond, Va.

SHIPPED: 5-6-58, from Brooklyn, N.Y., by Hall Pharmacal Co., Inc.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 400 milligrams of meprobamate per tablet.

LIBELED: 6-27-58, E. Dist. Va.

CHARGE: 502(a)—the statement on the drum label "For Investigational and Export Use Only" was false and misleading as applied to the article; and 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.